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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,928	08/06/2003	Balaji Venkataraman	52761-0110 (286146)	1053

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/635,928

Applicant(s)

VENKATARAMAN, BALAJI

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/26/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12, 15-19, 22-31 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12, 15-19, 22-31 and 33-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1623

DETAILED ACTION

This office action is mailed primarily to specifically indicate that claims 35-40 which were rejected in the prior office action of 12/22/06 (see page 5, 2nd paragraph to page 7, 1st paragraph) but was inadvertently omitted (as an oversight) from the 103 rejection heading statement on page 3 as been rejected, are now included in said rejection heading statement. It should be noted that these claims (claims 35-40) were also included as been rejected on the USPTO form-326 of the prior office action dated 12/22/06. Similarly, claims 35-40 are now presently included in the rejection under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. in view of Boros et al. or Boros of the prior office action (12/22/06), since they were inadvertently omitted (due to an oversight). It should be noted that no new references are added.

The following office action is a responsive to the Amendment filed, 09/26/05.

The amendment filed 09/26/05 affects the application, 10/635,928 as follows:

1. Claims 35-37 have been amended. Claims 6, 13, 14, 20, 21, 32 have been canceled. New Claims 44-47 have been added. This leaves claims 1-5, 7-12, 15-19, 22-31, 33-47. The office action mailed 12/22/06 is withdrawn.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-5, 7-12, 15-19, 22-31, 33-47 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1623

Claims 15-19, 22, 24, 30, 33 and 41-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “a condition associated with a hormonal change” in claims 15, 24 and 41-46, renders the claim indefinite. This phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what condition (s) are associated with a hormonal change and how must this or these condition be related to the hormonal change to be considered as being associated with the said hormonal change.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-12, 23, 25-29, 31, 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Kostic (Archiv fuer Gynaekologie (1965), 202 (1), pages 506-509).

In claim 1, applicant claims “A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6.” Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6,

Art Unit: 1623

and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3).

Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

Paradissis et al. disclose that their composition maximizes or optimizes fetal development and maintain the mothers health during the three trimesters of pregnancy (see abstract)

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as

Art Unit: 1623

women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women and depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Art Unit: 1623

In claim 35, applicant claims “A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C.” In claim 36, applicant claims “A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron.” In claim 37, applicant claims “A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron.” Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see col.7, line 45 to col. 8, line 16). Furthermore, Paradissis et al. disclose that this composition may comprise vitamin C and iron (see col.7, line 45 to col. 8, line 16) and that other component including vitamin E, Vitamin B₂ and B₃ may be absent (i.e., 0 mg) from the said composition (see col.7, line 45 to col. 8, line 16).

The difference between applicant’s claimed composition and the composition of Paradissis et al. is that applicant’s composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

Art Unit: 1623

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women and depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition,

Art Unit: 1623

the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 1-5, 7-12, 23, 25-29, 31, 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Boros et al. (Proceedings of the American Association for Cancer Research Annual Meeting, (March, 2000) No. 41, pp. 666. print. Meeting info.: 91st Annual Meeting of the American Association for Cancer Research. San Francisco, California, USA. April 01-05, 2000. ISSN: 0197-016X) or Boros (Anticancer Research, (2000) Vol. 20, No. 3 B, Pages 2245-2248).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxocobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid. Claim 35 is drawn to a composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C." In claim 36, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron." In claim 37, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron." Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

Art Unit: 1623

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

Paradissis et al. disclose that their composition maximizes or optimizes fetal development and maintain the mothers health during the three trimesters of pregnancy (see abstract). Furthermore, Paradissis et al. disclose that this composition may comprise vitamin C and iron (see col.7, line 45 to col. 8, line 16) and that other component including vitamin E, Vitamin B₂ and B₃ may be absent (i.e., 0 mg) from the said composition (see col.7, line 45 to col. 8, line 16).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Boros et al. disclose that vitamin B1 promotes cancer growth (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

Boros discloses that vitamin B1 excess thiamine supplementation contributes to increase cancer rates by enhancing tumor cell proliferation in people of different countries (see abstract and entire article). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

Art Unit: 1623

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Boros et al. or Boros to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with the high-risk pregnancies (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Boros et al. or Boros to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with the high-risk pregnancies (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a

Art Unit: 1623

combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 15-19, 22, 24, 30, 33, 41-45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Kostic (Archiv fuer Gynaekologie (1965), 202 (1), pages 506-509).

In claim 15, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 22 is drawn to the method of claim 15, wherein the hormonal change is caused by specific conditions. Claim 46 is drawn to the method of claim 15, wherein the condition with the hormonal change are specific conditions. Claims 24, 30, 33, 41-45, 47 are drawn to a method of treating a condition associated with said hormonal change using specific amounts or quantities of the components in the composition

Paradissis et al. disclose a of treating a condition associated with a hormonal change (pregnancies conditions in women) comprising administering to the individual an effective amount of a vitamin composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1). Paradissis et al. disclose that their composition maximizes or optimizes fetal development and the maternal mothers health during the three trimesters of pregnancy (see abstract). This implies that

Art Unit: 1623

Paradissis et al. treats or prevents the fetus underdevelopment and mother's health. It should be noted that pregnancies and the duration thereof are associated with hormonal changes. It should be noted that the cause of the hormonal change does not further limit the condition that is being treated. Furthermore, the condition treated by applicant includes high-risk pregnancy (see applicant's claim 46).

The difference between applicant's claimed method and the method of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical

Art Unit: 1623

history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Kostic to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that the use of specific amounts or quantities of the components in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated. It should also be noted that, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 15-19, 22, 24, 30, 33, 41-45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Boros et al. (Proceedings of the American Association for Cancer Research Annual Meeting, (March, 2000) No. 41, pp. 666. print. Meeting info.: 91st Annual Meeting of the American Association for Cancer Research. San Francisco, California, USA. April 01-05, 2000. ISSN: 0197-016X) or Boros (Anticancer Research, (2000) Vol. 20, No. 3 B, Pages 2245-2248).

Art Unit: 1623

In claim 15, applicant claims “A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6.” Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 22 is drawn to the method of claim 15, wherein the hormonal change is caused by specific conditions. Claim 46 is drawn to the method of claim 15, wherein the condition with the hormonal change are specific conditions. Claims 24, 30, 33, 41-45, 47 are drawn to a method of treating a condition associated with said hormonal change using specific amounts or quantities of the components in the composition.

Paradissis et al. disclose a of treating a condition associated with a hormonal change (pregnancies conditions in women) comprising administering to the individual an effective amount of a vitamin composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1). Paradissis et al. disclose that their composition maximizes or optimizes fetal development and the maternal mothers health during the three trimesters of pregnancy (see abstract). This implies that Paradissis et al. treats or prevents the fetus underdevelopment and mother’s health. It should be noted that pregnancies and the duration thereof are associated with hormonal changes. It should be noted that the cause of the hormonal change does not further limit the condition that is being treated. Furthermore, the condition treated by applicant includes high-risk pregnancy (see applicant’s claim 46).

Art Unit: 1623

The difference between applicant's claimed method and the method of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Boros et al. disclose that vitamin B1 promotes cancer growth (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

Boros discloses that vitamin B1 excess thiamine supplementation contributes to increase cancer rates by enhancing tumor cell proliferation in people of different countries (see abstract and entire article). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Boros et al. or Boros to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

Art Unit: 1623

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Boros et al. or Boros to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that the use of specific amounts or quantities of the components in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated. It should also be noted that, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

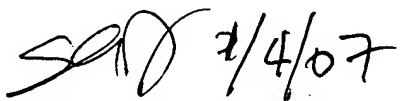
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry


Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

January 3, 2007.